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10/695,067	10/28/2003	J. Stewart Young	4002-3431	5993
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Woodard, Emhardt, Moriarty, McNett & Henry LLP Suite 3700 Bank One Center/Tower 111 Monument Circle Indianapolis, IN 46204-5137			CUMBERLEDGE, JERRY L	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/695,067	YOUNG ET AL.
	Examiner	Art Unit
	JERRY CUMBERLEDGE	3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 May 0208.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-63 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date, _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7, 10, 11, 16-20, 31-33, 43, 53, 56, and 58-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Jackson (US Pat. 5,980,523).

Jackson discloses a cross-connector assembly (Figs. 12-15) for interconnecting a pair of orthopedic rods, said assembly comprising: an interconnection element (Fig. 14, ref. 103) including a first body (Fig. 14, ref. 136) and a stud (Fig. 14, ref. 135), said first body having a first aperture (Fig. 14, ref. 138) formed therein and said stud extending from the body (Fig. 14); a first rod connector (Fig. 13, ref. 110, ref. 54) including a first shaft (Fig. 13, ref. 110) terminating in a first rod engaging portion (Fig. 13, near ref. 54) and a projection (Fig. 13, ridges of ref. 110)(Fig. 15, ridges of ref. 110) extending laterally from said first shaft (Fig. 15) and displaced axially along said first shaft from the spinal rod engaging portion (Fig. 13), said first shaft and said projection slideably received within the first aperture (Figs. 13-15); a second rod connector (Fig. 13, ref. 102) including a second shaft (Fig. 14, ref. 120) having a second body (Fig. 14, ref. 129) carried thereon (Fig. 14), said second body having a second aperture formed therein (Fig. 14, ref. 131), said second aperture having the stud received therein (Figs. 13, 14, Fig. 15); and a fastener configured to engage with the stud (Fig. 15, ref. 20).

Regarding the phrase “configured to engage with the stud”, the examiner is treating this as a functional statement that requires that the fastener be capable of touching (or engaging) the stud. The first aperture defines a first axis extending through the first body (Fig. 14, ref. 138) and the stud is positioned to lie substantially orthogonal to the axis (Fig. 14). The first aperture is non-circular (Fig. 14, ref. 138). The first shaft exhibits a substantially round cross-sectional profile, since the aperture is generally round, but somewhat eccentric (Fig. 14, ref. 138). The first rod engaging portion comprises a curved member (Fig. 13, near ref. 68) configured to at least partially encircle a spinal rod (Fig. 13). The first shaft is substantially straight (Fig. 13). The second shaft is curved (Fig. 13, above ref. numeral 120). The first shaft is slidably received within the first aperture to allow the first rod engaging portion to be spaced from the second rod engaging portion at varying distances (Fig. 13). The second shaft is rotatable about an axis defined by the stud to vary an angle defined by the first shaft and the second shaft (Figs. 12-15). The second aperture of the second shaft is configured to allow the second shaft to pivot along the axis defined by the stud (Figs. 12-15). The first rod connector is rotatable about an axis defined by the first shaft (Fig. 12-15). The second body on the second shaft includes a lower surface (Fig. 15, surface with splines that engages the splines of the rod), wherein engagement of the fastener to the stud urges the lower surface to contact the first shaft and clamp the first shaft in a first orientation relative to the second shaft (Fig. 15). The first rod connector is rotatable about an axis defined by the first shaft (Figs. 12-15). Rotation of the first rod connector induces the projection to contact said first body and inhibit removal of the first shaft from the first aperture (Fig.

14, Fig. 15). The first rod connector is rotatable about an axis defined by the stud (Fig. 14). The second rod connector is rotatable about an axis defined by the stud (Fig. 12-15). The first shaft is slidably received within the first aperture to allow the first rod engaging portion to be spaced from the second rod engaging portion at varying distances (Figs. 12-15). The assembly comprises a first spinal rod (Fig. 12, ref. 2) secured to the first rod engaging portion (Fig. 12) and a second spinal rod (Fig. 12, ref. 3) secured to the second rod engaging portion (Fig. 12). Engagement of the fastener to the stud secures the second rod connector in a selected orientation (Fig. 15). The assembly comprising a first spinal rod (Fig. 12, ref. 2) secured to the first rod engaging portion (Fig. 2) and a second spinal rod (Fig. 12, ref. 3) secured to the second rod engaging portion (Fig. 12). The first rod engaging portion comprises a hook (Fig. 13, near ref. 54) sized to at least partially encircle a spinal rod (Fig. 13), said hook extending laterally from the first shaft in a first direction (Fig. 13) and wherein said projection extends laterally from the first shaft along said first direction (Fig. 12-15). The projection defines a finger, lobe, or ridge (Fig. 15). At least one of the first shaft or the second shaft has a smooth exterior surface (Fig. 13, near ref. numeral 102) and a round or oval cross-sectional profile. The stud is monolithic with said body (Fig. 14). The stud has a longitudinal axis, and said first shaft has a longitudinal axis, and said stud longitudinal axis is oblique to said first shaft longitudinal axis (Fig. 12-15). The first shaft and said second shaft are capable of pivoting with respect to each other between a first position in which said first shaft and said second shaft are substantially parallel, and a second position in which said first shaft and said second shaft define an interior angle

between them that is less than 180 degrees (Figs. 12-15)(Figs. 24 and 25).

A method of treating a spinal defect, said method comprising: securing a first spinal rod and a second spinal rod each to two or more vertebrae; and interconnecting the first spinal rod to the second spinal rod using the assembly of claim 1 (Fig. 12).

Jackson discloses a cross connector comprising an interconnection element including a first body (Fig. 14, ref. 103) having an aperture (Fig. 14, ref. 138) formed therein and a stud (Fig. 14, ref. 135) extending from said body; a first spinal rod connector (Fig. 13, ref. 110, ref. 54) including a first shaft (Fig. 13, ref. 110) having a proximal end received within said aperture (Fig. 13) and a distal end carrying a first spinal rod engaging portion (Fig. 13, ref. 54) configured to at least partially encircle a spinal rod (Fig. 13); a second spinal rod connector (Fig. 13, ref. 102) having a second body (Fig. 14, ref. 129) on a proximal end, a second spinal rod engaging portion (Fig. 13, near ref. 116) on a distal end and a second shaft (Fig. 13, ref. 120) extending therebetween, wherein said body includes a second aperture (Fig. 14, ref. 131) having the stud received therein; and a single fastener (Fig. 13, Fig. 15, ref. 20) to secure the first and second spinal rod connectors to each other at a user defined orientation relative to each other (Fig. 13, Fig. 15). The first shaft comprises a protuberance (Fig. 13, ridges of ref. 110)(Fig. 15, ridges of ref. 110) extending laterally therefrom, said protuberance sized to be received within said first aperture (Fig. 13)(Fig. 15).

A method of treating a spinal defect, said method comprising: securing a first spinal rod and a second spinal rod each to two or more vertebrae; and interconnecting the first spinal rod to the second spinal rod using the assembly of claim 1 (Fig. 12)

With regard to statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over the device of Jackson which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 44, 45, 47-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiz (US Pat. 6,083,226) in view of Shluzas (US Pat. 6,554,832 B2).

Fiz discloses a cross-connector assembly for interconnecting a pair of orthopedic rods (Fig. 7), said assembly comprising: a first rod connector (Fig. 7, ref. 29) including a first shaft (Fig. 7, ref. 33) terminating in a first body (Fig. 7, near ref. 2) having a channel therethrough (Fig. 7, channel which ref. 2 sits in), a second rod connector (Fig. 7, ref.

30) including a second shaft (Fig. 7, near ref. 30) defining a longitudinal axis (Fig. 7) and terminating on a first end with a rod engaging portion (Fig. 7, near ref. 32) and on an opposite second end with a second body (Fig. 7, near ref. 34), said second body having a first aperture (Fig. 7, aperture which ref. 33 is placed in) therein defining a first central axis positioned to lie in a plane with but noncollinear with the longitudinal axis (Fig. 7), said second rod connector also including a second aperture (Fig. 7, ref. 36) therein defining a second central axis positioned to lie at an angle to the first central axis (Fig. 7); and a fastener (Fig. 7, ref. 35) extending through the second aperture of the second body (Fig. 7) and engaging one or more of the insert, the second body of the second rod connector, or the first shaft of the first rod to secure the orientation of the first rod connector relative to the second rod connector (Fig. 7). The first shaft of the first connector is straight (Fig. 7). The first aperture and the second aperture intersect (Fig. 7). The fastener engages with both the insert and the first shaft (Fig. 7). The fastener engages the insert thereby securing the first rod connecting member in a desired orientation relative to the second rod connecting member (Fig. 7). The fastener engages the first shaft thereby securing the first rod connecting member in a desired orientation relative to the second rod connecting member (Fig. 7). The fastener engages the second body of the second rod connector thereby securing the first rod connecting member in a desired orientation relative to the second rod connecting member (Fig. 7).

Fiz discloses the claimed invention except for an insert configured to engage the first shaft of the first rod connecting member extending through the first aperture and positioned in said second body and in communication with said second aperture.

Shluzas discloses a cross-connector assembly for interconnecting a pair of orthopedic rods (Fig. 2) that comprises an insert (Fig. 2, ref. 52) configured to engage a first shaft (Fig. 2, ref. 42) of a first rod connecting member (Fig. 2) extending through a first aperture (Fig. 2, ref. 40) and positioned in a second body (Fig. 2, ref. 30) and in communication with a second aperture (Fig. 2, aperture through which ref. 58 is placed). The insert creates a ball and socket type-joint (Fig. 2)(Fig. 4)(column 2, lines 33-34), which allows for pivotal movement of the rod connecting members relative to each other (Fig. 4) (column 2, lines 33-34) (column 2, lines 36-39) (column 2, lines 49-54) and further allows one rod connector to be slidable relative to the other rod connector (column 2, lines 39-44). This pivoting and sliding allows for greater adjustability and individualization of the device.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the device of Fiz with an insert as taught by Shluzas, in order to create a ball and socket type-joint (Fig. 2)(Fig. 4)(column 2, lines 33-34), which would allow for pivotal movement of the rod connecting members relative to each other (Fig. 4) (column 2, lines 33-34) (column 2, lines 36-39) (column 2, lines 49-54) and would further allow one rod connector to be slidable relative to the other rod connector (column 2, lines 39-44). This pivoting and sliding would allow for greater adjustability and individualization of the device.

Fiz in view of Shluzas disclose a method of treating a spinal defect, said method comprising: securing a first spinal rod and a second spinal rod each to two or more

vertebrae; and interconnecting the first spinal rod to the second spinal rod using the assembly of claim 44 (Fiz, Fig. 1)(Shluzas, Fig. 1)

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fiz (US Pat. 6,083,226) in view of Shluzas (US Pat. 6,554,832 B2) in view Burgess et al. (US Pub. 2003/0114853 A1).

Fiz in view of Shluzas disclose the claimed invention except for the first shaft and second shafts being curved so as to be non-linear. Fiz and Shluzas disclose that the shafts extend between and connect the rod engaging portions of the device to one another (Fiz, Fig. 1, Fig. 7) which in turn connects the spinal rods to one another (Fiz, Fig. 1, Fig. 7).

Burgess et al. disclose a cross-connector assembly for interconnecting a pair of orthopedic rods (Fig. 6) that comprise shafts that are curved (Fig. 6, refs. 84 and 82). The shafts are used to extend between and connect rod engaging portions of the device to one another (e.g. Fig. 1), which in turn connects spinal rods to one another (e.g. Fig. 1)(Fig. 6).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the linear shafts of Fiz in view of Shluzas with curved shafts as taught by Burgess et al. in order to achieve the predictable result of extending between and connecting rod engaging portions of the device to one another, which in turn connects spinal rods to one another.

Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (US Pat. 5,980,523).

Jackson discloses the claimed invention except for the first spinal rod is positioned to lie non-parallel/non-coplanar to the second spinal rod. Though Jackson does not explicitly state that the rods of the embodiment of Figs. 12-15 are positioned to lie non-parallel/non-coplanar to each other, Jackson discloses that the rods used in the device can be positioned to lie non-parallel to each other (Figs. 24 and 25). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the parallel rods shown as being used with the embodiment of Figs. 12-15 with the non-parallel rods as shown in Fig. 24 and 25, since Jackson discloses that the rods can be parallel (Figs. 12-15) or can be non-parallel (as shown in Figs. 24 and 25).

Claims 5, 6, 34, 35, 36, 54, 55 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (US Pat. 5,980,523) in view of Shluzas (US Pat. 6,554,832 B2).

Jackson discloses the claimed invention except for the first and second shafts are configured to nest with each other. The assembly comprises an insert configured to at least partially encircle said first shaft, said insert disposed within said first aperture. The insert in combination with the first aperture define a ball and socket joint. The assembly comprises an insert disposed within the second aperture, said insert configured to at least partially encircle said stud. The insert in combination with the

second aperture define a ball and socket joint. The insert is substantially spherical. The insert is substantially cylindrical. The apparatus comprises an insert positioned with the first body and configured to at least partially encircle the first shaft. The insert in combination with the first body restrict movement of the first shaft to inhibit disassembly of the apparatus. The apparatus comprises an insert positioned within the second body and configured to at least partially encircle the second shaft.

Shluzas discloses a cross-connector assembly (Fig. 2) that comprises first (Fig. 2, ref. 42) and second shafts (Fig. 2, ref. 30) that are configured to nest with each other (Fig. 2). The assembly comprises an insert (Fig. 2, ref. 50) configured to at least partially encircle said first shaft (Fig. 2), said insert disposed within a first aperture (Fig. 2, ref. 40). The insert in combination with the first aperture define a ball and socket joint (Fig. 2)(column 2, lines 32-35). The insert in combination with the second aperture define a ball and socket joint (Fig. 2)(Fig. 4). The insert is substantially spherical (Fig. 1). This connection creates a ball and socket type-joint (Fig. 2)(Fig. 4)(column 2, lines 33-34), which allows for pivotal movement of the rod connecting members relative to each other (Fig. 4) (column 2, lines 33-34) (column 2, lines 36-39) (column 2, lines 49-54) and further allows one rod connector to be slidable relative to the other rod connector (column 2, lines 39-44). This pivoting and sliding allows for greater adjustability and individualization of the device.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the device of Jackson with an insert as taught by Shluzas, in order to create a ball and socket type-joint (Fig. 2)(Fig. 4)(column

2, lines 33-34), which would allow for pivotal movement of the rod connecting members relative to each other (Fig. 4) (column 2, lines 33-34) (column 2, lines 36-39) (column 2, lines 49-54) and would further allow one rod connector to be slidable relative to the other rod connector (column 2, lines 39-44). This pivoting and sliding would allow for greater adjustability and individualization of the device.

Jackson in view of Shluzas disclose the claimed invention except for the insert being substantially cylindrical. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to have constructed the insert as being substantially cylindrical, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of providing an insert within an aperture of a cross-connector. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Jackson discloses the claimed invention except for the first rod engaging portion comprises a threaded aperture extending into the curved member.

Shluzas discloses a cross-connector assembly for interconnecting a pair of orthopedic rods (Fig. 2) that comprises threaded apertures (Fig. 2, near refs. 34 and 68) extending into rod engaging portions (Fig. 2, near ref. 32 and 66). These holes allow for a set screw to be placed that clamp a spinal rod to the rod engaging portions (column 2, lines 19-25). This better attaches the spinal rods to the cross-connector assembly.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the device of Jackson with threaded apertures as taught by Shluzas, in order to allow set screws to be placed that clamp a spinal rod to the rod engaging portions (column 2, lines 19-25). This would better attach the spinal rods to the cross-connector assembly.

Claims 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (US Pat. 5,980,523) in view of Shluzas (US Pat. 6,554,832 B2) in view of Papas (US Pat. 6,273,914 B1).

Jackson in view of Shluzas disclose the claimed invention except for the assembly comprises an insert disposed within the second aperture, said insert configured to at least partially encircle said stud. The insert in combination with the second aperture define a ball and socket joint.

Papas discloses a spinal fixation device (Fig. 1) that comprises a connection (Fig. 2) that comprises an insert (Fig. 2, ref. 96) at least partially encircling a stud (Fig. 2, ref. 72) and a fastener engaged with the stud (Fig. 2, ref. 18). This connection allows for multiple degrees of freedom (column 4, lines 50-54).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the connection mechanism of Jackson in view of Shluzas with a connection mechanism as taught by Papas, in order to allow for multiple degrees of freedom (column 4, lines 50-54).

Claims 8, 9, 12, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (US Pat. 5,980,523) in view Burgess et al. (US Pub. 2003/0114853 A1).

Jackson discloses the claimed invention except for the first shaft and second shafts being curved so as to be non-linear. Jackson discloses that the shafts extend between and connect the rod engaging portions of the device to one another (Fig. 12), which in turn connects the spinal rods to one another (Fig. 12).

Burgess et al. disclose a cross-connector assembly for interconnecting a pair of orthopedic rods (Fig. 6) that comprise shafts that are curved (Fig. 6, refs. 84 and 82). The shafts are used to extend between and connect rod engaging portions of the device to one another (e.g. Fig. 1), which in turn connects spinal rods to one another (e.g. Fig. 1)(Fig. 6).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the linear shafts of Jackson with curved shafts as taught by Burgess et al. in order to achieve the predictable result of extending between and connecting rod engaging portions of the device to one another, which in turn connects spinal rods to one another.

Regarding claim 23, Jacskson discloses the claimed invention except for the first spinal rod is positioned to lie non-parallel/non-coplanar to the second spinal rod. Though Jackson does not explicitly state that the rods of the embodiment of Figs. 12-15 are positioned to lie non-parallel/non-coplanar to each other, Jackson discloses that the rods used in the device can be positioned to lie non-parallel to each other (Figs. 24 and

25). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the parallel rods shown as being used with the embodiment of Figs. 12-15 with the non-parallel rods as shown in Fig. 24 and 25, since Jackson discloses that the rods can be parallel (Figs. 12-15) or can be non-parallel (as shown in Figs. 24 and 25).

Claims 13-15, 24-28, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (US Pat. 5,980,523) in view of Sherman et al. (US Pat. 5,976,135).

Jackson discloses the claimed invention except for a washer carried by the stud and positioned between the stud and the second aperture of the second rod connecting member.

Sherman et al. disclose a lateral connector assembly comprising a washer (Fig. 7, ref. 55) and the washer having splines (Fig. 7, ref. 60) and recesses (Fig. 6, ref. 58) and the second spinal rod connector having a lower surface (Fig. 11, ref. 72), which has a second set of splines (Fig. 11, ref. 82) which can matingly engage the splines of the washer, which allow the lateral connector to assume variable angular positions with respect to the washer (column 7, lines 1-19). The washer is made from a deformable material, since any material will deform when pressure is applied to it. The washer is capable of deforming when the fastener engages the stud. Engagement of the fastener can frictionally engage the washer to the first shaft of the first rod connector. The washer is capable of being carried by the stud and positioned between the stud and the

second aperture of the second rod connecting member. This set-up enables the lateral connector to assume variable angular positions with respect to the washer (column 7, lines 1-19).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the cross-connector assembly of Jackson with a washer and the washer having splines and the second spinal rod connector with a lower surface, which has a second set of splines of Sherman et al., in order to allow the lateral connector to assume variable angular positions with respect to the washer (column 7, lines 1-19).

Claims 1 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crozet et al. (US Pat. 6,217,578 B1) in view of Jackson (US Pat. 5,980,523).

Crozet et al. disclose a cross-connector assembly for interconnecting a pair of orthopedic rods, said assembly comprising: an interconnection element (Fig. 3, ref. 44) including a first body (Fig. 3, ref. 45) and a stud (Fig. 3, ref. 50), said first body having a first aperture formed therein (Fig. 4A, ref. 58) and said stud extending from the body (Fig. 3); a first rod connector (Fig. 3, ref. 30) including a first shaft (Fig. 3, ref. 28) terminating in a first rod engaging portion (Fig. 3, near ref. 18), said first shaft slideably received within the first aperture (column 5, lines 63-65); a second rod connector (Fig. 3, ref. 32) including a second shaft (Fig. 3, 34) having a second body (Fig. 3, ref. 36) carried thereon, the second body having a second aperture (Fig. 3, ref. 38) formed therein, said second aperture having the stud received therein (Fig. 3)(Fig. 2); and a

fastener (Fig. 3, ref. 56) to engage with the stud. The second aperture has a central axis (Fig. 3, 42) and the second rod connector has a channel for accommodating a spinal rod (Fig. 3, near ref. 14) said channel having a longitudinal axis (Fig. 3, along ref. 14), and said central axis and said longitudinal axis are perpendicular to each other (Fig. 3).

Crozet et al. disclose the claimed invention except for the projection extending laterally from the first shaft and displaced axially along the first shaft from the spinal rod engaging portion and the projection being slideably received within the first aperture.

Jackson discloses a cross-connector assembly that comprises projections extending laterally from a first shaft and being slideably received within a first aperture, the first aperture also having projections to engage with the projection of the first shaft (Fig. 13, ridges of ref. 110)(Fig. 14, ridges of ref. 142) (Fig. 15). The projections interengage to better lock the device from rotating when the device is properly placed within the patient (Fig. 15).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the device of Crozet et al. with projections as taught by Jackson, in order to better lock the device from rotating when the device is properly placed within the patient.

Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crozet et al. (US Pat. 6,217,578 B1) in view of Jackson (US Pat. 5,980,523) in view of Troxell et al. (US Pat. 7,137,986 B2)

Crozet et al. in view of Jackson disclose the claimed invention except for the interconnection element includes a pair of flanges extending diametrically opposite each other circumferentially about the first body, and the second body includes a pair of internal flanges in the second aperture, wherein the flanges of said interconnection element interengage with the flanges of the second body. Crozet et al. in view of Jackson do, however, disclose a connection mechanism that comprises threaded portions in order to lock the components together (Crozet et al., Fig. 3, ref. 50)(Fig. 2)

Troxell et al. disclose a coupling assembly comprising an interconnection element (Fig. 3, near ref. 16, 74) that comprises flanges (Fig. 10, near ref. 80) that extend into an aperture (Fig. 3, aperture through ref. 24) in order to lock components of the coupling assembly together (Fig. 3).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the connection mechanism of Crozet et al. in view of Jackson with a mechanism which utilizes flanges as taught by Troxell et al. in order to achieve the predictable result of locking components together.

Response to Arguments

Applicant's arguments filed 05/19/2008 have been fully considered but they are not persuasive.

With regard to Applicant's argument that Jackson does not disclose a projection, the examiner respectfully disagrees. The grooves cut into the circumference of ref. 110 form projections (best seen in Fig. 15, from cross-section).

With regard to Applicant's argument that the fastener does not and cannot engage with the stud, the examiner respectfully disagrees. Claim 1 requires "...a fastener configured to engage with the stud..." As explained above, the examiner is treating this as a functional statement that requires that the fastener be capable of touching (or engaging) the stud. Fastener ref. 20 is capable of being removed (see Fig. 15), and once removed can be placed into contact (or engage) with the stud.

With regard to Applicant's argument that the second body on the second shaft does not include a "lower surface", as the lower surface is actually a "side surface", the examiner notes that the surface can still be considered a lower surface. Initially, the surface can be named a "lower surface" if one so chooses to use that naming convention. Secondly, the surface can be oriented in a manner in which the surface is lower than other portions of the device (e.g. rotate ref. 102 of Fig. 15 90 degrees counterclockwise. As such, the surface can be considered to be a "lower surface".

With regard to Applicant's arguments directed toward at least one of the first shaft or the second shaft having a smooth exterior surface and a round or oval cross-sectional profile, the examiner notes that this occurs along the first shaft near ref. 111.

With regard to Applicant's argument that the longitudinal axes of the stud and the first shaft are perpendicular and are not oblique, the examiner notes that various axes can be placed through the portions of the device, some of which form an oblique relationship.

With regard to Applicant's arguments directed to the combination of the Jackson and Papas references, the examiner initially notes that the rejection is based on the

combination of Jackson, Papas and Shluzas and does not rely solely on the Jackson and Papas references. Jackson discloses the claimed invention except for the first and second shafts are configured to nest with each other and an insert, both of which Shluzas disclose. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the device of *Jackson in view of Shluzas* modifying the insert in the manner taught by Papas in order to allow for greater adjustability (*i.e.* more degrees of freedom). Furthermore, the examiner notes that the test for obviousness is not whether the features of one reference may be bodily incorporated into the other to produce the claimed subject matter but simply what the combination of references makes obvious to one of ordinary skill in the pertinent art. The combination of the references would provide the device with more degrees of freedom.

With regard to Applicant's argument that the Fiz and Shluzas references are not combinable, the examiner respectfully disagrees. By adding an insert feature as taught by Shluzas to the device of Fiz a ball and socket type-joint would be created, which would allow for pivotal movement of the rod connecting members relative to each other and further allows one rod connector to be slidable relative to the other rod connector. Similarly to the arguments directed to the previous combination of Jackson and Papas, this combination would also yield a device that has more degrees of freedom. Having extra degrees of freedom would be a benefit to the surgeon, as the surgeon would then have more customization options to work with as he performed the procedure.

With regard to the interpretation of the axes, the examiner notes that the previous interpretation was a valid interpretation. Furthermore, the longitudinal axis of the irregularly shaped second rod connector of Fiz can be considered to be along reference 34, along the bottom portion of the device, which is noncollinear with a central axis of the first aperture.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is

(571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./
Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733

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